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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,290	04/16/2002	Detlef Hasse	DAVI149.001APC	1731

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,290

Applicant(s)

HASSE ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-8, 10, 13, 14, 17, 19, 20 and 22-38 is/are pending in the application.
- 4a) Of the above claim(s) 22-38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 3, 6-8, 10, 17, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 13 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-4, 6-8, 10, 11, 13, 14, and 17-39 were pending in the application upon the mailing of the prior action on June 15, 2004. Claims 1-4, 6-8, 10, 11, 13, 14, and 17-21 and 39 were rejected, and claims 22-38 were withdrawn as to non-elected inventions. In the Response of February 23, 2005, claims 1-3, 6-8, 17, and 19 were amended; and claims 4, 11, 18, 21, and 39 were cancelled.
2. Currently, claims 1-3, 6-8, 10, 13, 14, 17, 19, and 20 are pending and under consideration. Claims 22-38 are pending and withdrawn from consideration.

Specification

3. **(Prior Objection- Withdrawn)** The specification was objected to as failing to provide proper antecedent basis for the claim limitations in claims 21 and 39. In view of the cancellation of these claims from the application, the objection is withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **(Prior Rejection- Withdrawn)** Claims 1-4, 6-8, 10, 11, 13, 14, 17-21, and 39 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The

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claims were rejected because it was not clear what polypeptides the Applicant considered to fall within the scope of the genus of OmpH proteins from *Lawsonia* spp.. In view of the amendment of the claims limiting them to the polypeptides of SEQ ID NO: 1, or having at least 70% identity thereto, the rejection is withdrawn.

6. **(Prior Rejection- Withdrawn)** Claims 6-8, 10, 11, 17, 18, 21, and 39 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims were rejected on two grounds. First, it was unclear if the claims read on a polypeptide of at least 70% identity to SEQ ID NO: 1 as a whole, or if the claims read on any polypeptide of at least 70% identity to only the corresponding region of the sequence. Second, the claims were rejected because it was not clear what distinguished the terms “peptide,” “oligopeptide,” and “polypeptide.” In view of the amendment of the claims to clarify that the claimed peptide must have at least 70% identity to the sequence of SEQ ID NO: 1 (i.e. to SEQ ID NO: 1 in its entirety), and to refer only to polypeptides, the rejection is withdrawn.

7. **(Prior Rejection- Withdrawn)** Claims 19 and 20 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for depending from a cancelled claim. In view of the amendment of the claims such that they now depend from claim 17, the rejection is withdrawn.

8. **(New-Rejection- Necessitated by Amendment)** Claim 10 is rejected under 35 U.S.C. 112, second paragraph as being indefinite for depending on a cancelled claim. The claim is currently drafted as depending from cancelled claim 9. Although the claim is marked as previously presented, the claim was previously dependant on claim 8. See, the Preliminary

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amendment of November 13, 2001. Thus, the claim appears to have been accidentally amended to depend from the wrong claim. Appropriate correction is required.

For the purposes of this action, the claim is treated as though it still depended from claim 8.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. **(Prior Rejection- Maintained)** Claims 1-4, 6-8, 10, 11, 17, 18, 21, and 39 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic polypeptides of SEQ ID NO: 1, does not reasonably provide enablement for any variant or homologue thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 4, 11, 18, 21, and 39 have been cancelled. Claims 1-3 have been amended to read on only polypeptides of SEQ ID NO: 1. The rejection is therefore withdrawn from these claims as moot or overcome by amendment.

However, claims 6-8, and 10 still read on variants of SEQ ID NO: 1 (requiring only 70% identity to SEQ ID NO: 1). While the Applicant asserts that the amendments to the claims have overcome the rejections, there has been no arguments or evidence presented to support that assertion with respect to the claims directed to any polypeptide of at least 70% identity to SEQ ID NO: 1. The rejection is therefore maintained for the reasons above, and the reasons of record.

11. **(Prior Rejection- Maintained)** Claims 1-4, 6-8, 10, 11, 17, 18, 21, and 39 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims were rejected as lacking sufficient written description support for the full scope of the claimed genus.

Claims 4, 11, 18, 21, and 39 have been cancelled. Claims 1-3 have been amended to read on only polypeptides of SEQ ID NO: 1. The rejection is therefore withdrawn from these claims as moot or overcome by amendment.

However, claims 6-8, and 10 still read on variants of SEQ ID NO: 1 (requiring only 70% identity to SEQ ID NO: 1). While the Applicant asserts that the amendments to the claims have overcome the rejections, there has been no arguments or evidence presented to support that assertion with respect to the claims directed to any polypeptide of at least 70% identity to SEQ ID NO: 1. The rejection is therefore maintained for the reasons above, and the reasons of record.

12. **(Prior Rejection- Maintained)** Claims 3, 8, 10, 17-21, and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic polypeptides or compositions comprising a peptide of an L intracellularis OmpH protein, does not reasonably provide enablement for any polypeptides of SEQ ID NO: 1, or derivatives thereof, capable of inducing a protective immune response or for vaccines comprising such polypeptides. The claims were rejected on the basis that the Applicant has not enabled the use of

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derivatives of SEQ ID NO: 1 as an immunogenic polypeptide, or the use of either SEQ ID NO: 1 or its derivatives to induce a protective immune response against *L. intracellularis*.

Claims 18, 21, and 39 have been cancelled from the application. The rejection is therefore withdrawn from these claims as moot.

With respect to claims 3, 8, 10, 19, and 20, although the rejection is withdrawn insofar as the claims were rejected for reading on derivatives of capable of inducing a protective immune response against *L. intracellularis*, the rejection is maintained because the claims still read on vaccines or protective compositions against *L. intracellularis*. The Applicant has not provided any arguments or other evidence to support a traversal of the rejection based on a lack of demonstrated protective effect. In view of the apparent complexity of the art as indicated in the prior action, the teachings in the art noting that killed and subunit vaccines of intracellular species had been largely unsuccessful despite numerous trials (see, Kroll et al., cited in the prior action), and the lack of evidence in the present application relating to the proteins protective effect, the rejection is maintained against the claims requiring a protective or vaccine efficacy.

The rejection is maintained on both grounds with respect to claim 17, which read on vaccines compositions comprising the polypeptide of SEQ ID NO: 1, or amino acids with at least 70% sequence identity thereto (i.e. derivatives of SEQ ID NO: 1).

13. **(Prior Rejection- Withdrawn)** Claims 13, 14, and 19 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The rejection was a rejection for **Deposit without a promise for availability**. In view of the submission of a

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Declaration noting the deposit of a cell containing the claimed plasmid, and containing the required statement of public availability, the rejection is withdrawn.

14. **(Prior Rejections- Withdrawn)** Claims 21 and 39 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement and written description requirements. In view of the cancellation of these claims, the rejections are withdrawn.

Conclusion

15. Claims 13 and 14 are objected to as depending on a rejected claim. Claims 1 and 2 are allowable over the prior art.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

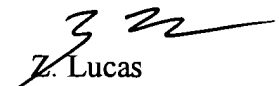
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


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3/7/05